Otto Bock
ORTHOPEDIC INDUSTRY, INC.

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SEP 1 8 2000

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	Otto Bock Orthopedic Industry, Inc.
2.	*Address:*	3000 Xenium Lane North Minneapolis, MN 55441
3.	*Telephone:*	612-553-9464
4.	*Contact Person:*	John Hendrickson
5.	*Date Prepared:*	February 10, 2000
6.	*Registration Number:*	2182293

B. Device

1.	*Name:*	Raebbit/Evolution Powered Wheelchair
2.	*Trade Name:*	Raebbit/Evolution Powered Wheelchair
3.	*Common Name:*	Powered wheelchair
4.	*Classification Name:*	Powered wheelchair
5.	*Product Code:*	ITI
6.	*Class:*	II
7.	*Regulation Number:*	890.3860

Otto Bock Orthopedic Industry, Inc.
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C. Identification of Legally Marketed Devices

1. *Name:* Ranger X
2. *K Number:* K852811
3. *Date Cleared:* August 22, 1985

D. Description of the Device

The Raebbit/Evolution is a wheelchair for active users. The wheelchair is manufactured in Thurnau, Germany, at a production facility of the OTTO BOCK Group. The Raebbit/Evolution is sold in Europe as the 'Raebbit' and will be sold/marketed in the United States as the 'Evolution.'

The Evolution has two groups of 24 gel batteries with Dynamic Controls electronics, capable of 4 mph for approximately 30 miles.

E. Intended Use Statement

The Raebbit/Evolution is mid or rear wheel drive powered wheelchair for active users. These wheelchairs provide mobility to physically challenged persons. The wheelchair can be moved by the user operating the remote control. The wheelchair can also be pushed by an assistant grasping the handles attached to the back rest.

F. Technological Characteristics Summary

The Raebbit/Evolution Wheelchair is substantially equivalent to the Invacare Ranger X Wheelchair, cleared on August 22, 1985 as K852811.

Each wheelchair is a powered wheelchair for the active user, with a rigid frame and similar characteristics.

The Raebbit/Evolution was tested by TÜV Product Service to the following standards:

- EN 292
- EN 1041
- prEN 12182
- EN 12184
- EN 60601-1-2
- EN/ISO 10993
- EN/ISO 9999
- ISO 7176-1

- ISO 7176-3
- ISO 7176-5
- ISO 7176-8
- ISO 7176-9
- ISO 7176-11
- ISO 7176-14
- ISO 7176-16
- ISO 7176-15
- ISO 7176-21
- VDE-0801
- IEC 801-2
- IEC 1000-4-3
- CISPR 22

with the conclusion that "the test sample fulfills the requirements."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Mr. John Hendrickson
CEO/President
Otto Bock Orthopedic Industry, Inc.
3000 Xenium Lane North
Minneapolis, Minnesota 55441

Re: K000678
Trade Name: Raebbit/Evolution Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: June 20, 2000
Received: June 21, 2000

Dear Mr. Hendrickson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: ~~*To be determined*~~ K000678

Device Name: Raebbit/Evolution Powered wheelchair

Indications for Use:

- Provide mobility to persons physically challenged and limited to sitting positions

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000678

Prescription Use _____ OR OVER-THE-COUNTER USE X
(optional Form 1-2-96)